

**Governance Workgroup**  
**Draft Transcript**  
**December 10, 2010**

**Presentation**

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Thank you. Mary Jo, you're our DFO?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I am your DFO, I believe, so why don't I take the roll call of the workgroup members who are present and anyone else who may be on the call. John Lumpkin?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Present.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Laura Adams? Christine Bechtel? I have Alice, is it Brown?

**Alice Brown – National Partnership for Women & Families – Director HITP**

Yes, I'm here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Carol Diamond?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Linda Fischetti? John Glaser? Leslie Harris? John Houston?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Michael Matthews? John Mattison?

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Girish Navani? Tim O'Reilly? Wes Rishel? Others on the call?

**Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability**

Doug Fridsma.

**Elliot Maxwell – ONC – Expert Contractor for Health IT**

Elliot Maxwell.

**Mariann Yeager – NHIN – Policy and Governance Lead**

Mariann Yeager.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Did I hear Stefaan? Are you on the call also?

**Stefaan Verhulst – Markle Foundation – Chief of Research**

Stefaan Verhulst, yes, I'm here.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Anyone else?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Mary Jo, it's Carol. Did you hear me? Were you able to hear me?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I did indeed, Carol. I have you present. Thank you. John, I believe that's it. Thank you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We had a series of slides that were sent out, and because of a conflict, we aren't Webcasting the slides, so we're going to bounce around a little bit. But after a few conversations, after our last meeting, and looking at the current slides, and going further, I wanted to sort of step back and suggest that using the feedback that we got from the last presentation to the Policy Committee is that our recommendations were perhaps a little bit too far into the forest. That what we should do is perhaps step back and have much higher level recommendations. So, if we do that, I think that we can submit what we've done as our deliberation for the edification of the staff within the Office of the National Coordinator, as they're developing the rules. I think we would also expect that, should be prepared just in case that we may, as a workgroup, get pointed inquiries and ask for our advice, as the process is ongoing. A reminder that when we all signed on, there was the possibility that we would be asked to review the notice of proposed rulemaking after it has been issued, and make additional comments to the Office of the National Coordinator.

Having said that, I would see that our recommendations would roughly fall into the following four categories, and this includes some things that we've already presented to the Policy Committee. The first would be our nine principles, principles of trust and interoperability. The second is that would be roughly saying, and we do have a slide on that, and we can cover that, is that the Nationwide Health Information Network would be the preferred option for the exchange of health information.

The third is that it would be the responsibility of the federal government to establish the conditions of trust and interoperability, and that this would be done in partnership with public or private entities that are qualified to do that. We have some of that as part of our discussion that we did on the conditions of trust and interoperability depending upon the type of range of conditions of trust and interoperability, some may be developed by SDOs and then adopted. Others may have different pathways to adoption. Then the fourth, that we would use a full range of federal authorities to assure conformance, in other words to do the validation, and that devolution of that validation would occur with federal responsibility for overseeing the process.

Those are the four overarching areas of recommendations that I would see us making on Monday to the Policy Committee. Are there any comments before we start going into some of the details? Okay.

I'm hoping that everybody has copies of the slides that were sent out yesterday by Mary Jo, and I'm just going to walk through these fairly quickly to get to the point where we do have some conversation. Starting on slide number six, we have the listing of the nine principles for governance, and those principles are also gone into in some detail. I'm sorry. I'm flipping through these slides.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Slides 36 to 40.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Thank you. Slides 36 to 40: The general recommendations would be on slide seven, which we've gone through a fair number of times, so I'm just going to try to walk through this, so if anyone has any issues, as I'm walking through quickly to get to where we want to discuss, please stop me. Then we have on slide eight our general objectives and functions.

The draft recommendations start on slide number 13, and these start off with the first one on slide number 14, which are the overarching recommendations, and this is the one that the federal government should provide strong leadership, and other governance entities have specific and appropriate roles related to governance. In other words, we see it as governance-to-governance, and that certain aspects of governance should apply across such as accountability and enforcement should apply across all governance roles.

The second slide, which would be our second main recommendation is that the health information network should be an environment of trust and interoperability for exchange based upon conditions of trust and interoperability and that should be the preferred approach, and that governance should apply when there's a validated compliance of all applicable conditions of trust and interoperability. When those who are exchanging health information assert they're doing so in the Nationwide Health Information Network environment.

We also made recommendations on what the federal role should be, which are consistent with what we've discussed before and presented on the 19<sup>th</sup>. Leveraging existing governance and enforcement mechanisms and recognizing existing state authorities, and so we're not going to go into the detail about the interplay between the federal government and states other than to comment that that needs to be addressed. That federal agencies should fully, participate fully and directly, including an appropriate governance mechanism, and this item particularly includes the fact that while we see a lead role for the Office of the National Coordinator, it's not an exclusive role in the governance process, and others, such as the VA and FDC and others, have a role to play. The federal agencies should meet the conditions of trust and interoperability, as other parties who are exchanging through that.

So that takes us onto slide 17 where we get into some of the detail about what the responsibilities of ONC, including facilitate coordination, establish core elements of the conditions of trust and interoperability, and oversee governance.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

John, you mentioned on slide 16 the role of additional federal agencies like the VA, and yet I don't see that captured. Am I missing it?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think what was intended is that federal agencies should, and then the first dash is participate fully and directly in the Health Information Network, including appropriate governance mechanisms, and so that's the broad federal should, and then we go on to slide 17 and talk about specifics for ONC.

**Linda Fischetti – VHA – Chief Health Informatics Officer**

Sorry I was put in the wrong Policy Committee for a little while there before I realized I needed to dial all the way back out and come back in. I'm very pleased with the way this has been restated, so thank you so much for making those changes.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Any other comments? Moving on to 17: That talks about the role of ONC to facilitate coordination, establish the conditions of trust and interoperability, and oversee governance. Then onto slide 18, I think, Mary Jo, all of these things are things that we've sent out before, but we're going to try to slim these down for the presentation.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Even further, I think. I think, if people are comfortable with them as they stand, one of the things we may do is judiciously, where possible, delete some of the sub-bullets. But again, as I think I said in my cover

e-mail, we want to make sure that in the appendix that we do have all of the full detail. It's just that we've been given very strong feedback that with the very limited time available on Monday, we should keep the language on the slides in the recommendations as simple and clear and crisp as possible without too many qualifiers.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

As you ....

**Mary Jo Deering – ONC – Senior Policy Advisor**

We won't lose it. So we won't ultimately lose it. It's just that it won't show up in the single recommendation statement.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Any questions on 17? Onto 18 then is that there should be a defined set of conditions of trust and interoperability. That the conditions of trust and interoperability should provide a baseline and address the need for variability, and that we would see that the governance role would establish an initial set of conditions of trust and interoperability and the framework for modifying them.

**Mary Jo Deering – ONC – Senior Policy Advisor**

You'll notice that that says it could be slightly modified if there's any additional aspect that the workgroup decides to add as a result of its consideration of the greater detail that was sent out during the week. But we ultimately need to roll it back up then into an acceptable, high level statement that the workgroup was comfortable with. It may be that this stands as it, but I just want you to know that we added that just as a placeholder for now.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Then that takes us to slide 19, which is the one that we've used before for examples of topics for the conditions of trust and interoperability. Based upon the feedback from the Policy Committee and certainly our discussions, you'll note that the recommendation that we made on going into detail on coordination is again no longer part of our recommendations. That item is just rolled into the statement that there is a need for coordination and that we see that as a federal role.

Then we move on to the slide 20, and again, I'm going through these, so please stop me if you do have comments. That once the conditions of trust and interoperability are established, a mechanism should be established to verify the conditions have been satisfied, in other words validation. It's defined as used to refer to the process for verifying compliance. This can include a broad range of possible methods, as we've talked about, and are included in the details that we've discussed that are in the appendices on slides— Do you remember, Mary Jo, what slides those are?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Well, it depends on how that's going to show up as a basis of the discussion because right now some of that detail is in the next section, which was put forward for the workgroup to discuss to make sure it was comfortable with the detail. Then eventually this section that we're just about to come to that's labeled for workgroup considerations will be recast, whatever the workgroup would like, and just put in the appendix.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I'd just ask a question on slide 19. I thought we took out eligibility criteria out of the slides with text.

**Mary Jo Deering – ONC – Senior Policy Advisor**

What we had said in one of the, but I guess it's now been dropped, where the way we worded it, we always had an asterisk that said the federal government should determine whether there are any factors which should disqualify an entity from being—I can't remember—eligible or from. We didn't use the word participation. Then we said temporarily or permanently. We did feel that was due diligence without trying to specify that it's like joining a club.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I remember that, but if you remember there were a lot of misinterpretations of this term without that qualifier, and if this is just an example slide, I would encourage you to just take out that in the list of examples without ....

**Mary Jo Deering – ONC – Senior Policy Advisor**

How about if we used the ...?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

I have an idea, Mary Jo and Carol. Would this work for everybody if we said eligibility/certification requirements, and then in brackets, the minimum necessary?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think that's a different concept here for this example slide.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I agree.

**Mary Jo Deering – ONC – Senior Policy Advisor**

But, Carol, what we could do is substitute for the qualifications to exchange through. We could put that explanatory caveat in there. Determine whether any factor might disqualify, and we could use might. Again, I think it's the concept that the federal government, as due diligence, needs to take a look at something like that. Would that make you more comfortable if we used it with that kind of language?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Yes, that's better.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Okay. That's what we'll do.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

I apologize, but could someone educate me to the difference between what you just agreed on and what I suggested because I don't see the difference, so I'm missing a nuance.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think we were getting at whether, for example, they were convicted felons. I don't mean to be too humorous, but I mean, it could be something that, are they under active investigation, or have they been convicted of Medicare fraud? There could be legal ... like that that we're talking about.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Let me just ask this question then. That's helpful. Are you saying that it may be an ad hoc determination because we don't want to specify everything that might be a disqualifier, but we want to have the opportunity to disqualify based on any credible evidence?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

No, I don't think we're describing the temporal nature of the disqualification. I think Mary Jo is just saying that one example of a condition for trust and interoperability maybe issues like this. In the reformulation of the bullet, she's suggesting adding it in a way that says there may be things like that that need to be considered as a condition for trust and interoperability. I don't think we've gone anywhere near the question of who and when and how.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think that's in keeping with this greater elevation of our discussion. I think we'll get into that kind of consideration, and you better watch out because if you raise it an issue, we may come back and ask you about it.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

That's very helpful. I got it. Thank you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

That takes us to 21, unless there are questions or comments on 20. It's a description of what the validation should be, including appropriate processes and criteria and maintain balance between assuring that the conditions of trust and interoperability have been satisfied, and the cost and burden of the validation process, and that there should be different pathways for validation. Any comments on 21?

Let's get into more of the detail that's being used to back up slide number 20 and 21, and so that will take us to slide number 29. I'm not going over the slides on conditions of trust and interoperability. We've sent those out. We've had opportunity to comment. We didn't get any. So unless there's something there, I'm going to move to slide number 29. This is the one that says the scope of the validation ....

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

John, I'm confused about what you just said. Did you say we're not doing those slides?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

The slides that we just went up to, to 21—

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Yes.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

—essentially represent what would be presented to the Policy Committee. Then the detail of what's in 25, 26, 27, and 28 would go into the appendix.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

The appendix of what?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

What we see doing is making the four high level recommendations to the Policy Committee, which they will then make to the ONC, as they're preparing the rules. I expect that what will happen is that ONC will be looking at not only the high level recommendations, but the text that we use in order to get to those high level recommendations, as they're going through their rulemaking process and considerations.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Okay, but what does that mean for what you're suggesting be put in the appendix? I'm not comfortable with that just going in the appendix if we don't discuss it.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

What I'm suggesting is that that was the e-mail that went out about—I think it was Friday of last week.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Actually, I think it was Monday night to Tuesday.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Monday night or Tuesday, and we asked people to comment on it so that we could not go back over the discussion we had on conditions of trust and interoperability in our call last week, but spend most of this call focusing in on validation. If there are comments on those slides, make them now.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Through e-mail, is that how you're getting them?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

No, I think right now because we need to get the slide set done by tonight, so if you have comments on them, speak now.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Well, do you want to go through them, or do you want me to just go through the individual slides? I don't want to derail the discussion if we have other materials we have to get to the workgroup or other discussion items. I'm just suggesting that ... to now is not an enormous amount of time, and there are other things going on, so I'm happy to go through them and send you something.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Thank you.

**Mary Jo Deering – ONC – Senior Policy Advisor**

If you could do it in real time because literally we are going to be starting at 2:31 to start revising these slides to finalize them, so we would appreciate some real fast turnaround, if you could.

**M**

And if there are some general principles that you're going to address on that, Carol, it might be good just to sort of throw them out now so that we have an idea of where you're going.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Great. You can move on, and I'll do my best.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Onto the validation slides that the validation is a process to verify that the conditions of trust and interoperability have been satisfied, that there are different methods for validation depending upon the nature of the conditions of trust, and we have two examples. For instance, looking at the technical requirements, which could involve technical testing or certification—validation that an entity meets requirements such as verifying appropriate identity proofing practices, for example. There may be different methods of validation depending upon the level of certainty needed to assure that a condition of trust and interoperability and other requirements are met, so this reflects our suggestion that there be a balance between the validation process and the cost of going through validation. Any comments on slide 29?

On 30, we say that the validation should leverage existing validation methods, processes, and entities where appropriate, and that validation by other entities such as states or other networks may satisfy the validation process. Any comments on slide 30?

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Yes. John, just a quick suggestion, I really liked what you said about balancing this against the costs and so forth, but I don't see that anywhere in the text. Is there a reason we don't just say we want to respect the burden of this effort and minimize it as much as possible?

**Mary Jo Deering – ONC – Senior Policy Advisor**

We originally actually have that in the current validation recommendation itself, and so I think what's going to happen is that given the strong suggestion that we streamline the recommendation slides as much as possible, that language, which is currently in the recommendation slide on slide 21, would indeed move back here to the greater detail.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

But, Mary Jo, I think, just for the time being because we haven't completely done that, I don't think it will hurt for that kind of very important statement to be redundant.

**Mary Jo Deering – ONC – Senior Policy Advisor**

So we should keep that kind of a statement in the main body. That's a good point.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes, I think it should be kept in the main body, and it should also be repeated here in what's going to go into the appendix. Other comments on 30? On 31, we have an example of the flow down. Any comments on that? So slide 32 talks about the federal responsibilities.

**M**

Just a quick question, and feel free to defer this, but is there a strong reason that we're excluding certification as opposed to validation?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Validation is the umbrella term that includes certification, accreditation, self-testing.

**M**

Is that clear elsewhere in the document?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Yes. That was in the definition. We put that in the definition of validation up front.

**M**

Thanks. I'm good. Keep going.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Can I ask another question too on 31, I guess it is?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Sure. Please.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

You just said it was obviously flow down from federal to validation bodies. Is there also some flow up for something in the opposite direction because I'm assuming that there needs then be coordination between all these bodies, which often may be at the state level, and other organizations who potentially could be passing information between organizations that are validated by separate validating entities, I guess is my ....

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

John, I like the idea, and what I'm wondering is the way to represent that might be to have one more flow, which is down from those to the actual entities, candidate participant entities, and then both, that last tier and the middle tier have feedback arrows that go into the upper right box with the Court of Appeals.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Got you. Okay.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Does that make sense to you?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

It does to me. I don't know. John Lumpkin is the one it has to make sense to.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

This is going to go into the appendix, so I won't have to defend this on Monday, so I'm good with it.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Let me ask Mariann, who is responsible for capturing this graphically if it's clear to her because you've just suggested adding a new tier on the bottom, correct?

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**



Yes, which is the entities that are subject to the second tier.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Right, and then there was an upward flow to the Court of Appeals, right?

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Not really a flow. I would make it more of a feedback loop off to the side.

**Mary Jo Deering – ONC – Senior Policy Advisor**

A feedback loop, right.

**John Mattison – Kaiser Permanente – Chief Medical Information Officer**

Both what is then the middle tier and the bottom tier both have feedback, so that if you show we've got self-corrected mechanisms in the flow.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Got you.

**Mariann Yeager – NHIN – Policy and Governance Lead**

That makes total sense to me, and just to reiterate that I'll add a third row to reflect those that are validated with an arrow or a feedback loop directly back to the federal government in the ....

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

The oversee box.

**Mary Jo Deering – ONC – Senior Policy Advisor**

In the Court of Appeals.

**Mariann Yeager – NHIN – Policy and Governance Lead**

Yes. Got it.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Any other comments on 31? Moving on to 32, which talks about the federal responsibility—including establishment of the criteria for validation, which are reflective of the COTIs, and a mechanism to authorize validation bodies. Once again, we talk about making sure that there's a balance between the validation and the cost and burden. Overseeing the validation bodies and serve as a Court of Appeals for decisions by validation entities.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

It also, I think ... my last point regarding that slide 31. Shouldn't there also be this federal responsibility for adjudicating between coordinating bodies or between—not coordinating bodies, but what you call these validation bodies?

**Mary Jo Deering – ONC – Senior Policy Advisor**

is it adjudicate or coordinate or both?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

I'm not sure what the right word is, but to my prior point, which is that you have all these different validating bodies at a state or local level doing this work. How do you pass and share information. Do you want to put that in the federal responsibility as well, that coordination of information that is developed?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think we can do that. In the last box in slide 31 under federal, if we put "oversee, coordinate validation efforts." In slide 32, we can maybe add an extra hash mark that talks about a coordination function, coordinating between the validation bodies.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Got you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We might be able to put that in the same way and hash number or dash number five, oversee when validation bodies and coordinate—coordinate and oversee validation bodies to insure that the goals and principles are met.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Got you. Much tighter.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Anything else on 32?

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

No.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I just wanted to tell you as a small item, in the third hash mark, establish a mechanism and a process by which, we need to delete the word “those.” It’s misleading. A process by which equivalent validations I recognize because there will be some existing validation bodies, and then there will be others that are deemed equivalent, so just as a minor, just to let you know that we’ll be deleting the word “those.”

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Not to mention there’s no antecedent to those anyway.

**Mary Jo Deering – ONC – Senior Policy Advisor**

It’s the grammar that caught me first, and then I realized it was downright wrong.

**M**

Maybe it might be even clearer if you say, “And a process by which existing and equivalent validations are recognized.”

**Mary Jo Deering – ONC – Senior Policy Advisor**

Okay.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay. Anything else on 32? Moving on to 33, responsibilities of the validation bodies to apply, establish ... applicable eligibility criteria, determine eligibility. Verify that practices are consistent. Verify that systems used to exchange meet the COTIs, including the technical requirements. Issue validation decision and investigate possible noncompliance.

**M**

Is it just investigate ... compliance?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

it’s investigate possible— I’m sorry. I was using shorthand. And take appropriate remedial action, including revoking the compliance recognition when warranted with provision for appeals.

**M**

Yes. I see it now. Thank you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Any comments on 33?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Did we address the accountability of the validation bodies anywhere? In other words, what happens when they don't do these things, or what process there'll be to deal with that?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We don't specifically, but we do say that the role of the federal responsibilities is to oversee the bodies through the goals and principles. We don't specifically say that would include taking remedial action.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Carol, I can only tell you based on what we've just gone through with our certification program that, believe me, what you've just said is understood. ONC must always retain the authority to take action against a body that it has authorized, so we're entirely with you on that.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I also was actually getting to preemptive policies in this regard around transparency that might be helpful in thinking about how to structure these. In other words, if there's a particular body that doesn't do a good job, knowing that early, making that transparent as opposed to some annual audit process is a good idea. There's just more thought that needs to go into that, but now is probably not the time.

**Mary Jo Deering – ONC – Senior Policy Advisor**

No, but I think that is a good point that rather than just necessarily an annual checkpoint, that you have a more real time and transparent process.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Other comments on 33? We have in 34 an example of approaches for identifying the validation bodies. This is based upon the document we had when what we were going to attempt to do was to present these two approaches to the Policy Committee with our recommendation. I think, at this point, we don't want to get that granular, but this looks, identifies that there are two processes. One, which ONC does the direct validation. That's approach one. Approach two where that, let's see, as I'm reading this too, that validation bodies may then be deemed by ONC.

**Mary Jo Deering – ONC – Senior Policy Advisor**

John, I'm thinking ....

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I'm looking at these, and I'm saying, they don't look that different.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Yes. Exactly. We almost, and to be very honest with you, we almost took them to.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Anybody want to keep this slide in?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Because we felt that the workgroup had actually expressed an opinion and these did not really clarify any choices. I think if everybody is in agreement with the prior slides ....

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Then we can just drop number 34.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Yes, unless the workgroup feels that it is indeed some choice to make.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Why do you think the choice is clarified in the previous slides, Mary Jo?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I'm saying that it seemed to me that the workgroup had—by spelling out what the federal government will do, it says that they are going to establish the criteria that, that they are going to establish a mechanism to authorize validation bodies. So you've left it at that higher level and a process by which existing and equivalent validations are recognized. So that lays out a sort of roadmap for what ONC should do.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Okay.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay. Anybody want to keep slide 34?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Only for the purposes of keeping the numbers consistent though.

**Mary Jo Deering – ONC – Senior Policy Advisor**

You're not going to recognize any of these numbers by the time we finish with you because, remember, a lot of what you have now agreed to, especially the specific changes that we've heard, we will now go back and recognize what is labeled appendices.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I appreciate that, Mary Jo. I just meant for the call since we're not Webcasting the slides.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes. It's there. I think— Mary Jo, are we done?

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think we are. I think that what we have said we would like to do is probably streamline the actual recommendations. John, with your permission, can I sort of read to you how I think the numbering may actually end up here?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay.

**Mary Jo Deering – ONC – Senior Policy Advisor**

If you recall that in October, we didn't actually get to a formal vote of the committee, so I'm sort of thinking that we'll have one formal recommendation on the principles. I'm thinking that we take what were called general recommendations, which are back on slide seven. We call that maybe a framework, and it becomes a formal recommendation, but I think before that, we might put the preferred approach, which is, I think, what you elevated to number two.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Right.

**Mary Jo Deering – ONC – Senior Policy Advisor**

So first could be the principles. Second would be the preferred approach. Next would be what we have on slide seven labeled general recommendations would be just called a framework. Then we would take moving to what you have as your draft recommendations. You have slide 14 called overarching, that sort of becomes federal leadership and shared responsibilities, as you've spelled out. Then specific federal responsibilities, and again, we'll tidy some of these up, specific ONC responsibilities. I think the slide having – then we have the COTIs, how they're established and our example, which we've just slightly tweaked for the eligibility criteria. Then we have the validation. I think that actually makes eight numbered recommendations within those four buckets.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

What I'd also like to suggest is that we take the slides that we've just gone through, and I know we're

going to tidy them up and tighten them up for the Policy Committee, but we want to make sure that I think repetition is okay in the appendix. Rather than moving stuff from those slides into the appendix, we move the entire slides into the appendix.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I see what you mean.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

So the appendix just becomes a greater exposition of our thinking.

**Mary Jo Deering – ONC – Senior Policy Advisor**

What I'm hearing is that we would have the full text of the recommendations, as they now look. We say here's the full text of the recommendations. Then, in addition, we would have this additional detailed two, three, four slides in some instances that support it. For example, the validation recommendation, as presented to the work, to the Policy Committee might be just the high level bullets, but we would take the whole detailed slide with its sub-bullets into the appendix, backed up by, for example, these slides that we just discussed that go into a little more detail about validation.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Right.

**Mary Jo Deering – ONC – Senior Policy Advisor**

This is ....

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Since we can, can we go back to some of those appendix slides that we skipped?

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Sure.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I'm confused about slide 26.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Which number?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Twenty-six. What is this? If you were explaining this slide, I realize there are three options considered, but what is considered mean, and what's the message we're trying to convey here?

**Mary Jo Deering – ONC – Senior Policy Advisor**

It's just that on the call last week, and maybe considered isn't quite the right word, there were three potential options that were placed on the table as a matter of fact that you could specify that all COTIs should be established in rulemaking, that COTIs should be established through other processes, or some mix of the above. When we thought about it, and again in trying to bump it up, we realized that on a de facto basis, it is going to be some mix of the above because some conditions of trust, especially those that are based on law, are always going to go through rulemaking.

On the other hand, there are things like standards and interoperability and some of the technical requirements that we've all worked very hard over the past year to take out of rulemaking. So you definitely want some of those COTIs to other processes. So it became obvious to us that, as a matter of fact, it was some mix. It was all of the above that was in fact the framework, and that's how we came up with this notion that, yes, there will be some that are established through rulemaking. And we recognize that there will be a lot of work to be done by ONC and that may well be an area that we come back to you on in saying, exactly now where is that bar placed.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Is ONC deciding where these COTIs get established, because if this is – the way you're describing it, I think you see this slide exactly the way you saw slide 34 as examples of how things could be done, but in fact what we've already said is more clear than this. I personally would like to see then this taken out because it implies these options were considered for the COTIs in ways that I don't think we considered them. It's to say that ONC is going to make those determinations for the COTIs, which is, I think, what we said in the other slide is fine.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Maybe the thing to do is focus really vigorously on slide 28 and see if you're comfortable with that because that's where it's all pulled together as a slightly more detailed exposition of what we thought we heard—what we thought ....

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Right, but, Mary Jo, I don't see any problem with deleting slide number 26.

**Mary Jo Deering – ONC – Senior Policy Advisor**

No, absolutely. I got an X mark through it already.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Okay.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

If we delete that, the only thing I wanted to suggest then on 28 is that I don't think, in the first bullet, framework really speaks to what we want. I think what we discussed and what is in the slide and described is a process that solicits multi-stakeholder coordinated input, whatever. The framework there word throws me.

**Mary Jo Deering – ONC – Senior Policy Advisor**

I think the reason we used it was as a sort of higher order construct to say exactly what you probably just said is that there's going to be a combination of rulemaking in other processes. We're lumping all those under the term framework was all.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I guess I'm saying framework doesn't say that to me. I'd rather see this be COTIs and a process for multi-stakeholder and public input or something that would speak to this.

**Mary Jo Deering – ONC – Senior Policy Advisor**

That would certainly be much more direct.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Yes.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think though that, Carol, by focusing on the word framework and changing that, we lose what you were also suggesting, which is talking about the importance of multi-stakeholder input, which I don't see on slide 28 at all. I agree, it should be on there.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

That's why I'm suggesting replacing that word with a more specific statement about what we mean in establishing COTIs. I also don't know why it says initial set, by the way.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Well, that was, the feeling was that if you— It's a question of timing and how quickly we need some governance to be operational. If nothing is established through rule except that the clock then starts

ticking, the process of actually getting to an identified set of COTIs that could then trigger the whole process could be delayed by—you know the rulemaking process.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I understand that. It's just that this slide, I thought, was meant to describe the process, and I think the process is not, we're not describing it for only an initial set. We're describing a process, and if what results from the Policy Committee discussions and deliberations and our own deliberations is an acceptance of this process, it would be very good to translate that into, within 90 days, an initial set of COTIs are established to cover these prioritized areas or what have you. As opposed to the way it reads here, which is, we're describing a process, but it's only for an initial set.

**Mary Jo Deering – ONC – Senior Policy Advisor**

No, actually it isn't. It says, an initial set and a framework in which new or modified. So it is both. In fact, the way this first read was, you know, the NPRM should establish.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I took new and modified to mean additions or modifications to the initial set, not necessarily that the initial set is meant to cover all of the ground and then it's an ongoing process, but whatever.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Yes. Let me suggest a solution here because I think we're trying to cram too much into one slide. I could see a slide that would be between 27 and 28 that would talk about the importance of multi-stakeholder input. That would identify that in order to facilitate exchange that the COTIs that are ready to go should be adopted, and that subsequent COTIs may be adopted through processes described, defined by ONC, which would include maybe a broader set, and would include modifications and so forth. But we indicate in the separate slide the importance of stakeholder input and that it's going to be a multi-phased process. Does that work?

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

I think so. I'm not sure I followed all of that. I was hoping we could have fewer slides rather than more, but if we could clarify what we mean, both by the process, and by the word framework in slide 28, that that would be a good thing, however you see fit to do that.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

I think we have the ideas that you're raising, and I will be seeing the draft and trying to make sure that we work them in.

**Mary Jo Deering – ONC – Senior Policy Advisor**

We'll do our very best. I guess I would say it doesn't matter if you have more slides rather than less in the appendix because the importance of the appendix is to make sure. We doubt that very many people will read it, but ONC will have it. So I don't think we're trying to necessarily streamline what's in the appendix. If it's important that we make some point there, then we certainly will.

**Carol Diamond – Markle Foundation – Managing Director Healthcare Program**

Speaking as a member of one of these committees, I always read the appendix.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Good for you. I know you will. I'm actually going to send them out as two separate decks so that we don't ....

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Confuse them.

**Mary Jo Deering – ONC – Senior Policy Advisor**

... a little bit more manageable.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We've got six minutes. Do we have anything else we need to do?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Just to reiterate, we will be sharing with John as rapidly as possible a new draft deck or two decks. We have heard the guidance that we can remove some of the sub-bullets from the actual deck, from the actual wording of the formal recommendations, but that that slides in their full entirety will be added to the appendix. That we will take some of these slides that were in the middle here that we've just discussed, and we'll find a way to logically present them as backup to the recommendations.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. I guess, at this point, since we've— Do we have public comment?

**Mary Jo Deering – ONC – Senior Policy Advisor**

Operator, I think we should ask if there are any public comments.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

While she's opening that up, let me thank all of you. It's been a great roller coaster ride. I thank you so much for your diligence and input, and digging in your heels when necessary, so I think we've got a very good work product as a result of it and wish everyone a great set of holidays.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

You too, John. Thank you.

**Mary Jo Deering – ONC – Senior Policy Advisor**

And as staff, I would certainly like to add my thanks and appreciation for all of the hard work. It was certainly over and above the call of duty.

**Alison Gary – Altarum Institute – Communication Technologies Coordinator**

Operator, do we have any public comment?

**Coordinator**

There are no comments at this time.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Great. Thanks, everyone.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Thank you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

We'll send you out what we're going to be presenting.

**John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security**

Thank you.

**John Lumpkin – Robert Wood Johnson Foundation – SVP & Director**

Good-bye.

**Mary Jo Deering – ONC – Senior Policy Advisor**

Bye-bye.

**W**

Thank you.